A Partnership Including Professional Corporations 600 Thirteenth Street, N.W. Washington, D.C. 20005-3096 202-756-8000 Facsimile 202-756-8087 www.mwe.com

Marc E. Sorini Attorney at Law msorini@mwe.com 202-756-8284 Boston Chicago London Los Angeles Miami Munich New York Orange County Silicon Valley Washington, D.C.

DERMOTT, WILL & EMERY

October 21, 2003

and Delivery

'illiam Foster
Regulations & Procedures Division
ol & Tobacco Tax & Trade Bureau
tment of the Treasury
G Street, N.W.
ington, DC 20005

Re: Information Request Pursuant to the Federal Data Quality Act

Mr. Foster:

Diageo North America, Inc. ("Diageo") respectfully requests that the Alcohol & Tobacco & Trade Bureau ("TTB") correct or withdraw certain information as required by the Federal Quality Act ("FDQA"), Public Law 106-554 § 515. Diageo makes this request under the A, implementing regulations issued by the Office of Management and Budget ("OMB"), 67 Reg. 8452 (Feb. 22, 2002), and implementing guidelines issued by both the Department of ury and TTB. Per my October 16, 2003 discussion with Robert Tobiason, I direct this letter a because it is not yet clear who TTB's designated official is under the FDQA.

TTB Notice Number 4, a notice of proposed rule-making regarding flavored malt ages and related proposals ("Notice 4"), asserts that current labels on flavored malt ages ("FMBs") confuse consumers with respect to both the source and amount of alcohol in everages. 68 Fed. Reg. 14292, 14296-97 (Mar. 24, 2003). Based on these assertions, Notice poses sweeping changes in the regulation of FMBs. *Id.* at 14296. As explained below, to believes that Notice 4 violates the FDQA because it does not adequately ensure the quality assertions of consumer confusion and does not provide any supporting data for those ions. Diageo accordingly requests that TTB either: (1) publish the data supporting Notice

required agencies to publish FDQA guidelines on or before October 1, 2002. 67 Fed. Reg. 8452, 8459 (Feb. 02). Thus, TTB's FDQA Guidelines were promulgated by ATF before the division of ATF and TTB on y 24, 2003. Treasury Order 120-01 provides that all administrative actions completed by ATF on or before y 23, 2003 "shall continue in effect until superseded or revised." 68 Fed. Reg. 3583, 3584 (Jan. 24, 2003). as apparently not published any revisions or superseding guidelines. The FDQA Guidelines originally need by ATF therefore continue to govern TTB's dissemination of information.

4's assertions of consumer confusion, if any, and permit Diageo and the public the opportunity to submit comments on the data, or (2) withdraw those assertions.

I. SUMMARY OF REQUEST

Notice 4 asserts that "to label a beverage that derives most of its alcohol content from added alcohol flavors as a malt beverage is inherently misleading since consumers would expect that malt beverages derive a significant portion of their alcohol content from fermentation of barley malt and other ingredients at the brewery." *Id.* at 14296. Notice 4 provides *no* scientific or statistical support – such as consumer surveys or other evidence – for this assertion. Despite the lack of any factual support, Notice 4 uses this assertion to justify its proposed "standard for malt beverages that limits the alcohol content derived from alcohol flavorings and other materials to less than one-half of one percent alcohol by volume...." *Id.*

Notice 4 also asserts that consumers are confused about the strength of the alcohol in some FMBs. Notice 4 claims that some FMBs' "label appearance and the use of the brand names of well-known distilled spirits" confuse consumers into believing they have higher alcohol content than they do. *Id.* at 14296. Notice 4 also claims that other FMBs' supposed resemblance to "nonalcoholic new age beverages such as juices, sodas, bottled water, and energy drinks," confuses consumers as to whether they contain any alcohol at all. *Id.* at 14297. Again, Notice 4 provides no scientific or statistical support for this assertion, but uses that assertion to justify a proposed requirement that FMBs and only FMBs disclose their alcohol content.

Asserting consumer confusion without any factual support violates the FDQA and its implementing regulations. The FDQA requires that TTB ensure the quality of information that it generates and disseminates to the public. Quality further requires that TTB (1) ensure that the information is accurate and reliable and (2) provide appropriate supporting documentation. Notice 4's failure to present any documentation to support its assertions of consumer confusion violates these requirements.

II. BACKGROUND

A. Notice 4's Assertions of Consumer Confusion

Notice 4 asserts that "to label a beverage that derives most of its alcohol content from added alcohol flavors as a malt beverage is inherently misleading since consumers would expect that malt beverages derive a significant portion of their alcohol content from fermentation of barley malt and other ingredients at the brewery." 68 Fed. Reg. at 14296.

Based on this assertion, Notice 4 proposes "a standard for malt beverages that limits the alcohol content derived from alcohol flavorings and other materials to less than one-half of one percent alcohol by volume..." 68 Fed. Reg. at 14296; see also id. at 14301 (proposing Section 7.11(a)). Notice 4's proposed new standard significantly changes current federal policy. Id. at 14296 ("[A]ny standard applied would be a substantial change from existing regulations and policy..."). Among other things, these changes would "affect[] the rate of tax applicable to [FMBs], the premises where they may be produced, the way they are labeled, advertised,

marketed, and the distribution system by which they are sold to retailers and consumers." *Id.* at 14294; *see also id.* at 14301-03 (proposing changes in the regulations). Notice 4's assertions of consumer confusion will likely influence state regulators, and its proposed new standard, if adopted, would likely result in additional significant changes in state regulation and oversight. *Id.* at 14294.

Notice 4 also asserts that FMBs confuse consumers about their alcohol strength in two different ways. First, Notice 4 asserts that as a result of some FMBs' "label appearance and the use of the brand names of well-known distilled spirits, we believe that consumers are likely to be confused as to their actual alcohol content." *Id.* at 14296. Notice 4 hypothesizes that consumers believe these FMBs have a high alcohol content. *Id.* Second, Notice 4 claims that other FMBs that supposedly resemble "nonalcoholic new age beverages such as juices, sodas, bottled water, and energy drinks," are "likely to confuse consumers as to their identity as alcohol products." *Id.* at 14296-97. The foregoing speculations prompt Notice 4 to propose a requirement that FMBs, but not other malt beverages, bear a statement showing their alcohol content.² *Id.* at 14297; *see also id.* at 14301 (proposing section 7.22(a)(5)).

B. The Absence of Any Evidence Supporting Notice 4's Assertions of Consumer Confusion, and the Existence of Substantial Evidence Contradicting Them

Notice 4 provides no scientific, statistical, or other evidentiary support for its assertions of consumer confusion. 68 Fed. Reg. at 14296-97. Further, (1) TTB's own prior findings contradict Notice 4's assertions of consumer confusion; and (2) the available scientific statistical evidence also contradicts those assertions.

1. TTB's Prior Findings

In 1996-97, TTB's predecessor agency, ATF, undertook a rulemaking project to ascertain whether federal law should prohibit or restrict the use of distilled spirit cocktail names in the labeling and advertising of malt beverages. See 61 Fed. Reg. 57597 (Nov. 7, 1996). That Advanced Notice of Proposed Rulemaking ("cocktail cooler rulemaking") generated over 5,000 comments, including several substantial surveys on the subject of consumer perceptions of malt beverages bearing well-known cocktail names. Based on a careful analysis of the evidence submitted, ATF decided not to pursue further rulemaking on the subject. On the question of consumer confusion, the Agency concluded:

Evidence introduced indicates that flavored malt beverages are viewed by consumers as coolers or low alcohol refreshers, and not as a distilled spirits product. Evidence introduced also indicates that the presence of distilled spirits

² Notice 4's proposed standard for determining which beverages must carry an alcohol content label will produce strange results. The trigger Notice 4 proposes for deciding when a malt beverage must state alcohol content – the presence of non-beverage flavors or other sources of alcohol – is not reasonably related to supposed confusion. See 68 Fed. Reg. at 14301 (proposing Section 7.22(a)(5)). Existing products made without non-beverage flavors or other alcohol sources have labeling and packaging features that TTB claims may lead to consumer confusion about alcohol content. Conversely, many flavored products might have none of the labeling or packaging features that Notice 4 claims may mislead consumers about alcohol content.

or any similarity of these products to a distilled spirits drink is not a criteria in their selection by consumers.

Letter to William L. Webber, from Arthur J. Libertucci, dated Nov. 17, 1997, Exhibit A, at 2.

In other words, just six years ago ATF concluded, after a formal notice-and-comment procedure, that consumers do not care about the alcohol source in FMBs. If, as ATF found, consumers do not care about the source of the alcohol in FMBs, then the source of alcohol will not affect their buying decisions and a malt beverage label will not mislead them into buying a beverage they would otherwise not buy. See IQ Prods. Co. v. Pennzoil Prods. Co., 305 F.3d 368, 376 (5th Cir. 2002) (holding that a representation is material only if it affects the buying decisions of consumers); 15 U.S.C. § 1125(a)(1)(B) (materiality requirement for Lanham Act claims). Thus, the Agency's prior finding that consumers do not care about the source of the alcohol in FMBs contradicts Notice 4's current assertion that consumers are misled by malt beverage labels on such beverages.

Similarly, in 1983 ATF determined that comprehensive ingredient labeling "is not justified since it appears that the indiscriminate disclosure of such information would not be useful and is not of substantial interest to the consumers generally." 48 Fed. Reg. 45549, 45551 (Oct. 6, 1983). If the ingredients of an alcoholic beverage are not of substantial interest to consumers, then it follows that consumers are not interested in the source of the alcohol in such beverages and would therefore not be misled in the manner Notice 4 asserts.

2. Available Scientific Statistical Evidence

Evidence presented during the cocktail cooler rulemaking demonstrates that ATF correctly concluded that alcohol source is not material to consumers purchasing FMBs. According to a 1995 consumer survey by E. & J. Gallo Winery, when consumers were asked why they bought Bartles & James Margarita Flavored Beverage, less than one-half of one percent of survey respondents mentioned that they thought the product contained tequila or other distilled spirits. See E. & J. Gallo Winery, Comment No. 926 on ATF Notice 844 (Feb. 3, 1997), Exhibit B, at 9. The survey respondents cited the product's lemon/lime taste and the Bartles & James brand name as the principal reasons for their selection of Bartles & James Margarita Flavored Beverage, not their perception that the product contained distilled spirits. Id. Overall, the Gallo survey determined that the source of alcohol in Bartles & James Margarita Flavored Beverage was immaterial to purchasing consumers. Id. at 10-11.

Likewise, according to a 1995 consumer survey by Joseph E. Seagram & Sons, Inc., only two out of 226 purchasers surveyed described Seagram's Margarita Flavored Coolers as containing tequila, and only one purchaser out of 226 stated that s/he selected the product because it contained tequila. See Joseph E. Seagram & Sons, Inc., Comment No. 902 on ATF Notice 844 (Feb. 3, 1997), Exhibit C, at 10. For 99% of the purchasers of Seagram's Margarita Flavored Coolers, the source of alcohol in the product was irrelevant to their purchasing decision. Id. Thus, available evidence shows that consumers do not care about the source of the alcohol in FMBs.

III. DISCUSSION

A. The FDQA Requires Quality Information

The FDQA requires that TTB "ensur[e] and maximiz[e] the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency..." 67 Fed. Reg. at 8458. "Information" includes "any communication or representation of knowledge such as facts or data, in any medium or form..." *Id.* at 8460.

The FDQA's quality requirement requires that TTB ensure the objectivity of both the presentation and the substance of the information it disseminates. *Id.* at 8459. TTB must ensure objectivity in its presentation of information by presenting it "in an accurate, clear, complete" manner. *Id.* This means that TTB must:

identify ..., in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, the data should have full, accurate, transparent documentation....

Id. (emphasis added). Further, TTB must also ensure objectivity in the substance of information by:

ensuring accurate, reliable ... information. In a scientific, financial, or statistical context, the <u>original and supporting data shall be generated</u>, and the analytic results shall be developed, using sound statistical and research methods.

Id. (emphasis added).

The FDQA further requires even greater assurances of quality where TTB disseminates "influential scientific, financial, or statistical information." Id. at 8460 (emphasis added). For influential information, TTB must provide "a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." Id. Information is "influential" where the "dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." Id.

Pursuant to OMB's regulations, both Treasury and TTB have promulgated FDQA guidelines. See Subdivision of Treasury Information Technology (IT) Manual ("Treasury Guidelines"), Ch. 14: Information Quality; Process for Requesting Correction of Information Disseminated by the Bureau of Alcohol, Tobacco & Firearms ("FDQA Guidelines"). These guidelines incorporate and adopt OMB's requirements regarding quality. Treasury Guidelines, § 14.4.2; FDQA Guidelines, at 2. They also adopt OMB's definition of influential information. Treasury Guidelines, § 14.4.3; FDQA Guidelines, at 3.

B. Diageo Is an Affected Person with Standing to Request a Correction

Any "affected person" may request that TTB correct information that it has publicly disseminated. *FDQA Guidelines*, at 3. An affected person is any person "who may benefit or be harmed by the disseminated information." *Id*.

Diageo is an affected person because it may be and, indeed, is likely to be harmed by the incorrect information regarding supposed consumer confusion disseminated in Notice 4. That information is presented as justification for far-reaching changes in the policies affecting FMBs. As a producer of such beverages that developed FMBs in reliance on existing federal policy, Diageo will be harmed by the implementation of regulations that impose more stringent limits on the percentage of non-beverage flavors in such products. Further, the incorrect information will likely influence state regulators, who may take adverse regulatory action against FMBs in reliance on Notice 4's unsupported assertions of consumer confusion.

C. Notice 4's Assertions of Consumer Confusion Constitute "Information"

"Information" includes "any communication or representation of knowledge such as facts or data" 67 Fed. Reg. at 8460; *Treasury Guidelines*, Appx. A – Definitions; *FDQA Guidelines*, at 2. Notice 4 presents its assertions of consumer confusion as fact, 68 Fed. Reg. at 14296-97, and they therefore constitute "communications or representations of knowledge."

Courts uniformly treat assertions of consumer confusion as questions of fact. See, e.g., PPX Enters. v. Autofidelity Enters., Inc., 818 F.2d 266, 271 (2d Cir. 1987) (consumer confusion a question of fact in Lanham Act cases); Scandia Down Corp. v. Euroquilt, Inc., 772 F.2d 1423, 1427-28 (7th Cir. 1985) (same). Thus, Notice 4's assertions of consumer confusion are representations of knowledge and fact and therefore constitute "information" under the FDQA and implementing regulations.

D. Notice 4's Assertions of Consumer Confusion Do Not Meet the FDQA's Quality Requirements

The FDQA does not allow Notice 4 to represent, without any scientific or statistical support, that labels for FMBs are misleading and confusing to consumers. Instead, it must provide data to support its claims to satisfy the FDQA's quality requirements.

Objectivity in Presentation:

The FDQA requires agencies to provide data supporting factual assertions so that "the public can assess for itself whether there may be some reason to question the objectivity of the sources." 67 Fed. Reg. at 8459; see also Treasury Guidelines, § 14.4.2(A); FDQA Guidelines, at 2. Yet Notice 4 cites no consumer surveys, studies, or any other evidence to support its assertion that FMB labels are misleading and cause consumer confusion. Thus, it fails to provide any supporting data and, as a result, the public cannot assess the quality of the information. Notice 4 accordingly fails to satisfy the FDQA's requirement of objectivity in presentation.

Objectivity in Substance:

The FDQA requires that Notice 4 provide "accurate, reliable" information, and "[i]n a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods." 67 Fed. Reg. at 8459; see also Treasury Guidelines, § 14.4.2(B); FDQA Guidelines, at 2. Notice 4's assertions of consumer confusion occur in a scientific and statistical context because such assertions usually must rely on scientific statistical studies for support. See, e.g., Conopco, Inc. v. Cosmair, Inc., 49 F. Supp. 2d 242, 252 (S.D.N.Y. 1999) (explaining that courts must often rely on "scientific surveys which test the statistical likelihood of consumer confusion"). But Notice 4 does not provide any scientific or statistical data to support its assertions, let alone data generated using "sound statistical and research methods." As a result, Notice 4 fails to satisfy the FDQA's requirement of objectivity in substance.

Notice 4's assertions of consumer confusion accordingly violate the FDQA and its implementing regulations and guidelines. To remedy this situation, Diageo requests that TTB either (1) publish the scientific and statistical support for Notice 4's assertions, if any exists, and permit Diageo and the public the opportunity to submit comments on that support, or (2) withdraw Notice 4's assertions, if no such support exists. Publication of statistical support in a final rulemaking will not satisfy this request, because the Administrative Procedures Act requires that TTB give adequate notice of, and opportunity to comment on, the factual data supporting a proposed regulation. *E.g.*, *Fla. Power & Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988) (notice insufficient because it did not include the factual basis for the proposed regulation); *Lloyd Noland Hosp. & Clinic v. Heckler*, 762 F.2d 1561, 1565-66 (11th Cir. 1985) (same); *Conn. Light & Power Co. v. Nuclear Reg. Comm'n*, 673 F.2d 525, 530-31 (D.C. Cir.), *cert. denied*, 459 U.S. 835 (1982) ("An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.").

E. Notice 4's Assertions of Consumer Confusion Do Not Comply with the FDQA's Heightened Requirements for Influential Information

Notice 4's assertions of consumer confusion qualify as "influential scientific, financial, or statistical information" under the FDQA and therefore are subject to even higher quality requirements than those just discussed. Information is "influential" where the "dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." 67 Fed. Reg. at 8460; see also Treasury Guidelines, § 14.4.3; FDQA Guidelines, at 3. Notice 4's representations will have a clear and substantial impact on both important public policies and important private sector decisions.

Notice 4's representations will affect important public policies in two respects. First, Notice 4 uses the representations to justify proposed sweeping changes in federal policy affecting FMBs. As Notice 4 itself states, its proposed changes in the regulation of FMBs would "affect[] the rate of tax applicable to them, the premises where they may be produced, the way they are labeled, advertised, marketed, and the distribution system by which they are sold to retailers and consumers." 68 Fed. Reg. at 14294. Second, Notice 4's consumer confusion allegations may well influence state regulators, causing them take regulatory action adversely affecting FMBs in

reliance on those allegations. Thus, Notice 4's representations of consumer confusion "will have ... a clear and substantial impact on important public policies" at both the federal and state level.

Notice 4's representations of consumer confusion also will substantially affect "important private sector decisions." Its proposed change in regulations will affect the economic and business decisions of Diageo and many other companies. Thus, Notice 4's representations of consumer confusion are "influential" under the FDQA.

Notice 4's representations of consumer confusion also constitute scientific and statistical information. As noted above, assertions regarding consumer confusion are statistical in nature because they usually must rely on scientific statistical studies for support. See, e.g., Conopco, Inc., 49 F. Supp. 2d at 252. Because Notice 4's assertions likely can only be shown through "scientific surveys which test the statistical likelihood of consumer confusion," id., those assertions constitute influential scientific and statistical information under the FDQA.

The FDQA requires that when TTB disseminates influential scientific or statistical information, it must provide "a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." 67 Fed. Reg. at 8460; see also Treasury Guidelines, § 14.4.2(B); FDQA Guidelines, at 3. As discussed above, Notice 4 does not provide any scientific or statistical data to support its representations of consumer confusion. Because Notice 4 fails to satisfy even the normal requirements for quality and transparency, see Part III.C. supra, it follows that it also fails to meet the heightened requirements for influential information.

IV. CONCLUSION

Notice 4's assertions of consumer confusion violate the requirements of the FDQA and implementing regulations and guidelines. Diageo therefore requests that TTB either (1) publish supporting data, if any, that complies with the requirements of the FDQA and permit Diageo and the public the opportunity to submit comments on that data, or (2) withdraw Notice 4's representations of consumer confusion if no such supporting data exists.

Sincerely,

Marc E Sorini

Mh E fin

Enclosures

cc:

John Blood (by fax w/o encl.) Gary Zizka (by fax w/o encl.)

Jason A. Carey

WDC99 817861-2.049298.0077